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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,742	10/07/2003	John T. Stults	29191-704	8150
21971	7590	08/10/2004	EXAMINER	
WILSON SONSINI GOODRICH & ROSATI 650 PAGE MILL ROAD PALO ALTO, CA 943041050			LEYBOURNE, JAMES J	
			ART UNIT	PAPER NUMBER
			2881	

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/681,742	STULTS ET AL.	
	Examiner	Art Unit	
	James J. Leybourne	2881	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>0708&0713</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Specification

Information Disclosure Statement

1. The information disclosure statement filed July 08, 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Only the US patents have been considered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prosser et al. (US 202/0110902A1) in view of Mordehai (US 20040108455). Prosser et al. disclose an electrospray ionization device that comprises an electrospray microfluidic chip 82 mounted to a chip holder 4 (Fig. 8). The chip holder 4 includes a chip holder

drive system [0054] and alignment mechanism that includes a mechanical device that moves the tip end into correct position [0055].

Linear motion stages allow for movement of this entire assembly in front of the mass spectrometer to allow the device to be positioned optimally for maximum performance of the mass spectrometer while the electrospray is active. In conjunction with feedback from the mass spectrometer signal, these stages of movement allow for automation optimization of the position of the electrospray with respect to the detector [0071]. It would be obvious to one of ordinary skill in the art to use the detected ion signal from the mass spectrometer as the feedback signal.

As shown in FIG. 1, an assembler control system **120** is coupled by electrical leads **121** to a controller box **122**. The controller box includes a microprocessor, power supply for the drive motors, control voltages and electrospray voltages for the electrospray chip. The assembler control system **120** includes a central processing unit (CPU) or processor, a memory and may comprise other components [0058]. If the ionization voltage of the electrospray ionization source is applied between the emitter and the orifice of the mass spectrometer, it would be obvious to one of ordinary skill in the art to connect the power supply to the mass spectrometer orifice.

Prosser et al. do not teach using a calibration solution for optimizing the parameters of the ESI device. Mordehai teaches the use of standard calibration mix sample introduced through a standard electrospray nebulizer [0024]. As admitted in the specification [0004] it is known in the art to optimize the Electrospray experimentally using either a calibrant solution or sample solution

4. Claims 12-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bousse et al. (US 2004/0113068). Bousse et al. disclose a microfluidic chip formed with multiple fluid channels terminating at a common electrospray ionization tip for mass spectrometric analysis. The fluid channels may be formed within a substrate plate that are in fluid communication with corresponding reservoirs (abstract). A calibration solution may be selected among these fluids to adjust the operating conditions of the ESI tip before the sample under test is analyzed. The calibration solution can be used in automating this process of adjusting and optimizing the positioning or conditions of the electrospray, including the physical location of the tip relative to the mass spectrometry instrument and the applied voltage.

Bousse et al. do not teach how the optimization process can be automated. As admitted in the specification [0004] it is known in the art to optimize the Electrospray experimentally using either a calibrant solution or sample solution and observing a number of characteristics including the Taylor cone, increased analyte signal(s), reduced background signals, greater signal stability, greater spray stability and greater spray current.

In order to automate optimization of the ESI device, as taught by Bousse et al., it would be obvious to one of ordinary skill in the art to measure one or more of the parameters that are used during manual setup and automatically adjust at least one of the ESI interface conditions.

Bousse et al. teach microfluidic chips are formed with a number of microchannels that are connected to a variety of reservoirs containing fluid materials [0003]. The

microfluidic devices available today can conveniently provide mixing, separation, and analysis of fluid samples within an integrated system that is formed on a single chip [0003]. A preferable embodiment of the invention provides microfluidic chips that are formed with individual fluid channels. These fluid channels extend through the body of the microfluidic chip and converge at a common distal tip region [0007].

As known in the art, when calibrating ESI-MS systems, calibrant solutions can be introduced separately into the system, followed by the analyte to be characterized, they can be introduced simultaneously using multiple emitters or they can be introduced simultaneously by mixing the solutions.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James J. Leybourne whose telephone number is (571) 272-2478. The examiner can normally be reached on M-F 9:00- 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John R Lee can be reached on (571) 272-2477. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

July 28, 2004
JJL

Lee
SP
Au2881